

DETAILED ACTION

Status of the Claims

Claims 1 and 3-13 are pending.

Claim 2 has been cancelled.

This is in response to applicant's amendment filed on 10/13/09.

Objection to the claims

The objection to claim 1 has been withdrawn.

Claim Rejections - 35 USC § 112

The rejection of claim 1 under 35 U.S.C 112 second paragraph has been withdrawn in view of the amendment to the claim. However, a new rejection follows.

Claim Rejections - 35 USC § 102

The rejection of claim 1 under 35 U.S.C 102 (b) has been withdrawn in view of applicant's arguments and/or remarks.

Claim Rejections - 35 USC § 103

The rejection of claims 1 and 3-13 under 35 U.S.C 103 over JP-A 02-172956 in view of Noyori et al., and JP-06-080617 has been withdrawn. However, a new rejection follows.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 1624

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-13 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/795,035 has been withdrawn.

Response to Amendment/Remarks

Response to applicants argument is moot in view of the withdrawal of the 112, second paragraph rejection and the obviousness-type double patenting rejection and the new rejection under 35 U.S.C. 103.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The consistent use of the word “arbitrarily” in defining the invention renders the scope of the invention indeterminate since, if permitted, it would leave the invention to chance.

Art Unit: 1624

Note the dictionary meaning of arbitrarily is "determine by chance, whim, or impulse, and not by necessity, reason, or principle". It is suggested that applicants modify the language of the claims to eliminate the term "arbitrarily" to terms which find support in the specification which particularly and distinctly point out that which applicants intend as the invention specifically.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

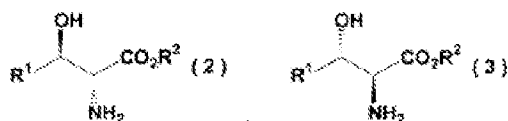
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP A 02-172956 in view of Labeeuw et al., Assymetry; Tetrahedron, 15; pages 1899-1908 (2004).

Applicants claim a process for making optically active β -hydroxy- α -aminocarboxylic acid of formulae (2) or (3), comprising subjecting α -aminoacyl acetic acid ester of formula (I) to hydrogenation by catalytic asymmetric hydrogenation in the presence of an acid.

1. (Currently Amended) A process for producing optically active β -hydroxy- α -aminocarboxylic acid derivative of formula (2) or (3)



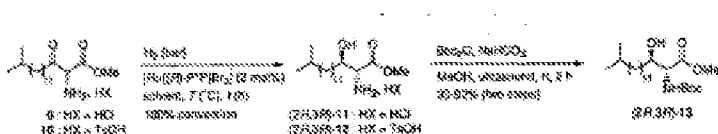
Determination of the scope and content of the prior art (MPEP §2141.01)

JP-'956' teach the preparation of β -hydroxy- α -aminocarboxylic acid of formulae (2) or (3), comprising subjecting α -aminoacyl acetic acid ester of formula (I) to hydrogenation by catalytic asymmetric hydrogenation in the presence of an acid. See the entire reference especially page 381.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

JP-'956' differs from the current process in that the use of Group VIII metal complex with phosphine ligand is not required. However, Labeeuw et al., teach the preparation of optically active β -hydroxy- α -amino carboxylic acid by ruthenium-phosphine complex catalyzed by asymmetric hydrogenation. See the entire publication, especially scheme 5, reproduced below:

Art Unit: 1624



Note the claimed catalyst i.e., ruthenium complex and that of Labeeuw et al., are all hydrogenation catalyst complexes and similar and as such can be interchanged with a reasonable expectation of success .

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

Accordingly, at the time of filing this application, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare β -hydroxy- α -aminocarboxylic acid of formulae (2) or (3), from the specified reagents and guided by the knowledge in the art and Labeeuw et al., that catalysts such as Group VIII metal ligand complex are used for hydrogenation and with a reasonable expectation that the resulting products would be pure because Labeeuw et al., and “956” teaches hydrogenation using a ruthenium-phosphine catalyst complex similar to the current one employed in the instant process. Hence, one in possession of ‘956’, guided by the knowledge in the art is in possession of the instant process absent a showing of unexpected results or properties. The process that is being claimed is a predictable and expected process. Thus, the use of asymmetric catalysts in the instant process is *prima facie* obvious.

Accordingly, the instantly claimed process would have been suggested to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EBENEZER SACKKEY whose telephone number is (571)272-0704. The examiner can normally be reached on 7.30-4.30.

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Ebenezer O. Sackey/
Patent Examiner, AU 1624**

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**